

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA**

Plaintiff, by and through the undersigned counsel, hereby brings this Complaint for damages against the Defendants, and alleges the following:

INTRODUCTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drug Levaquin® (also known as levofloxacin). Levaquin® in any of its forms shall herein be referred to as "Levaquin." Plaintiff maintains that Levaquin is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings and directions as to the dangers associated with its use.

PARTIES

2. Plaintiff Gordon C. Olsommer is a natural person and at all relevant times a resident and citizen of Pike County, Pennsylvania. Plaintiff brings this action for personal injuries sustained by the use of Levaquin. As a direct and proximate result of being prescribed and ingesting Levaquin, Plaintiff developed peripheral neuropathy.

3. Defendant Johnson & Johnson is a New Jersey corporation that has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

4. Defendant Johnson & Johnson has transacted and conducted business within the State of Pennsylvania.

5. Defendant Johnson & Johnson has derived substantial revenue from goods and products used in the State of Pennsylvania.

6. Defendant Johnson & Johnson expected or should have expected its acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

7. Defendant Johnson & Johnson was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

8. Defendant Janssen Research & Development, LLC is a New Jersey limited liability company with its principal place of business in New Jersey.

9. Defendant Janssen Research & Development, LLC has transacted and conducted business within the State of Pennsylvania.

10. Defendant Janssen Research & Development, LLC has derived substantial revenue from goods and products used in the State of Pennsylvania.

11. Defendant Janssen Research & Development, LLC expected or should have expected their acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

12. At all times material hereto, Defendant Janssen Research & Development, LLC was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

13. Defendant Janssen Research & Development, LLC is part of the Defendant Johnson & Johnson's "Family of Companies."

14. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation which has its principal place of business in New Jersey.

15. Defendant Janssen Pharmaceuticals, Inc. has transacted and conducted business within the State of Pennsylvania.

16. Defendant Janssen Pharmaceuticals, Inc. has derived substantial revenue from goods and products used in the State of Pennsylvania.

17. Defendant Janssen Pharmaceuticals, Inc. expected or should have expected their acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

18. At all times material hereto, Defendant Janssen Pharmaceuticals, Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

19. Defendant Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson.

20. As used herein, "Defendants" includes all named Defendants.

21. Defendants are authorized to do business in Pennsylvania and derive substantial income from doing business in this state.

22. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities with Pennsylvania, thus invoking the benefits and protections of its laws.

23. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture and/or distribute Levaquin, with full knowledge of its dangerous and

defective nature.

JURISDICTION AND VENUE

24. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the amount in controversy exceeds \$75,000, exclusive of interest and costs, and because Defendants are all either incorporated and have their principal place outside of the state in which the Plaintiffs resides.

25. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1337.

26. Venue is proper in this Court pursuant to 28 U.S.C. § 1331 in that Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell, market and/or distribute Levaquin within Pennsylvania and this District.

FACTUAL ALLEGATIONS

27. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are responsible for Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the pharmaceutical drug Levaquin.

28. Plaintiff was prescribed Levaquin (500mg) on or around June 17th and July 8th of 2010 for bronchitis and a sinus infection and used it as directed. Shortly thereafter, Plaintiff began suffering symptoms of peripheral neuropathy and was subsequently diagnosed with peripheral neuropathy.

29. Plaintiff's use of Levaquin in 2006, 2007 and 2010 caused or substantially contributing to his developing peripheral neuropathy.

30. Levaquin was approved by the United States Food and Drug Administration (hereinafter "FDA") on December 20, 1996, for use in the United States, and is the brand name for the antibiotic levofloxacin.

31. Levaquin is a broad-spectrum fluoroquinolone antibiotic used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria.

32. In 2003, after generic versions of Cipro (a competing fluoroquinolone antibiotic)

went on the market, Levaquin became the number one prescribed fluoroquinolone in the United States.

33. In 2006, after generic versions of Zithromax, a highly popular macrolide antibiotic, went on the market, Levaquin became the number one prescribed antibiotic in the world.

34. In 2007, Levaquin was ranked 37 of the top 200 drugs that were prescribed in the United States.

35. In 2007, Levaquin was ranked 19th in world sales of prescribed drugs.

36. In 2007, Levaquin accounted for 6.5% of Johnson & Johnson's total revenue, generating \$1.6 billion in revenue, an 8% increase over the previous year.

37. Defendant Janssen Pharmaceuticals, Inc. indicates on its website that “[i]n a large number of clinical trials, Levaquin has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections.”

38. However, the scientific evidence has established a clear association between Levaquin and an increased risk of long-term and sometimes irreversible peripheral neuropathy.

39. Defendants knew or should have known that Levaquin is associated with an increased risk of developing irreversible peripheral neuropathy.

40. Defendants failed to appropriately and adequately inform and warn Plaintiff and Plaintiff's prescribing physicians of the serious and dangerous risks associated with the use of Levaquin concerning peripheral neuropathy, as well as other severe and personal injuries, which are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish, diminished enjoyment of life, and the need for medical treatment, monitoring and/or medications.

41. The warning label for Levaquin during the period from September 2004 through August 2013 misled Plaintiff and his treating physician by incorrectly advising patients and physicians that peripheral neuropathy associated with Levaquin was “rare” and in any case could be avoided by discontinuing the drug upon the onset of certain symptoms. The truth, however, is

that the onset of irreversible peripheral neuropathy is often rapid and discontinuation of the drug will not ensure that the peripheral neuropathy is reversible.

42. Though this injury can be significant and debilitating, the language regarding the “rare” risk of peripheral neuropathy was buried at the bottom of a long list of adverse reactions that were included on the Levaquin label; the language was in no way highlighted for the benefit of prescribing physicians and patients.

43. Additionally, Defendants failed to disseminate a “Dear Doctor” letter to physicians concerning the label change or the risk of irreversible peripheral neuropathy, and Defendants failed to disclose this serious and dangerous effect when promoting Levaquin to physicians.

44. Despite their knowledge that Levaquin was associated with an elevated risk of permanent nerve damage, Defendants’ promotional campaign was focused on Levaquin’s purported “safety profile.”

45. As early as 1990, there was evidence of the association between quinolone drugs and peripheral neuropathy. Dr. Chan, et al. published an article reviewing 27 patients treated with the quinolone Peflox for urinary tract infections. One of the 27 patients developed peripheral neuropathy that resolved four weeks after discontinuation of Peflox. This case represents a positive “de-challenge.”

46. In 1992, there was evidence of the association between fluoroquinolone antibiotics and peripheral neuropathy. Dr. Aoun from the Infectious Diseases Clinic and Microbiology Laboratory at the Institut Jules Bordet in Belgium, along with others, wrote a letter to the editor of the Lancet raising concerns about a 37-year old patient who developed peripheral neuropathy after taking fluoroquinolones.

47. A single well-documented case report can be viewed as a safety signal, particularly if the report describes a positive re-challenge.

48. In the pharmaceutical industry, safety signals indicate the need for further investigation.

49. After a signal is identified, it should be further assessed to determine whether it represents a potential safety risk that should be included in product label.

50. Four years later, in 1996, Karin Hedenmalm and Olav Spigset published “Peripheral sensory disturbances related to treatment with fluoroquinolones” based on a review of 37 separate reports of symptoms of peripheral nerve damage, highlighting concerns about numbness, pain, and muscle weakness.

51. One of the first studies in the United States that included the post market experience concerning Levaquin and neuropathy was “Peripheral Neuropathy Associated with Fluoroquinolones” written by Jay S. Cohen.

52. The Cohen paper was published in December 2001 and revealed that adverse events reported by forty-five patients suggested a possible association between fluoroquinolones and long-term peripheral nervous system damage. The study noted in particular the presence of severe and/or persistent nerve problems. Over one-half of the patients surveyed said their symptoms lasted for more than a year, and eighty percent characterized their symptoms as severe. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy. The study concluded with the following advisory: “If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for these drugs’ product information.”

53. In 2002 and 2003 Defendants were put on notice that numerous reports had been submitted to the FDA’s Adverse Event Reporting System that identified fluoroquinolone users who had developed disabling peripheral neuropathy that persisted long after the drug had been discontinued.

54. A scientific review by the FDA of the adverse events in the FDA Adverse Event database in 2003 concerning Levaquin and other fluoroquinolones revealed numerous reports of long-term peripheral neuropathy.

55. In September 2004, an amended Levaquin label concerning peripheral nerve

damage was approved by the FDA. The amended label included the following statement in the Warnings section:

Peripheral Neuropathy: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesia, dysesthesias and weakness have been reported in patients receiving quinolones, including levofloxacin. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation in order to prevent the development of an irreversible condition.

56. Thus, rather than warning patients and physician that the use of Levaquin may result in permanent nerve damage, Defendants instead adopted a warning that misleadingly indicated such damage was rare and in any event could be avoided by simply discontinuing the drug upon the onset of certain symptoms.

57. Defendants' failure to adequately warn physicians resulted in (1) patients receiving Levaquin instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which Plaintiff presented to the provider; (2) and physicians failing to warn and instruct consumers about the risk of peripheral nervous system injuries associated with Levaquin.

58. The failure of Defendants to include appropriate warnings in the label as published to the medical community also resulted in an absence of adequate warnings in patient information presented directly to consumers, either as part of samples packages or as part of the prescription they received from retail pharmacies.

59. Despite Defendants' knowledge and failure to adequately warn Plaintiff and his physicians of the above, Defendants continue to market Levaquin as a first line therapy for common bronchitis, sinusitis and other non-life threatening bacterial infections, conditions for which many other safer antibiotics are available.

60. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that the

existing warning regarding peripheral nerve damage was inadequate. On August 15, 2013, an updated warning was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included. The updated warning also removed the statement that nerve damage occurred only in rare cases.

61. Notwithstanding this updated 2013 label change, the label for Levaquin remains inadequate and confusing regarding the risk of developing irreversible peripheral neuropathy following the use of Levaquin.

62. For instance, the Levaquin label currently states under the “Warnings and Precautions” section of the first page as follows: “Peripheral neuropathy: discontinue immediately if symptoms occur in order to *prevent irreversibility* (5.8).” This statement implies to physicians and patients that, if the patient stops using the drug immediately after symptoms occur, the symptoms are reversible. However, in section 5.8, the label states that “[s]ymptoms [of peripheral neuropathy] may occur soon after initiation of LEVAQUIN® and *may be irreversible*.” This later statement conflicts with the earlier statement by implying that no matter whether the patient stops using the drug immediately after experiencing symptoms, the symptoms may be permanent. It is inconsistent to advise physicians and patients in one section of the label that the symptoms of peripheral neuropathy are reversible if the drug is stopped immediately after symptoms occur, but to advise physicians and patients in another section of the label that symptoms may be irreversible no matter whether they stop taking the medication immediately upon experiencing symptoms.

63. In January of 2014, Ayad Ali published “Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis” which reemphasized the link between fluoroquinolones and peripheral neuropathy and called for increased scrutiny of the risk-benefit of fluoroquinolone prescriptions. The Ali paper also detailed the presence of strong safety signals dating back to at least 2005 regarding the potential for Levaquin and other fluoroquinolones to cause long-term, disabling peripheral neuropathy.

64. An epidemiologic study published in the August 2014 online edition of *Neurology* provided further quantitative support for the association between fluoroquinolone antibiotics and peripheral neuropathy.¹ The study compared 6,226 cases of peripheral neuropathy among men ages 48-80 to 24,904 controls and determined that those on fluoroquinolones were at a statistically significant higher risk of developing peripheral neuropathy (RR = 1.83, 95% CI: 1.49-2.27), with current users having the highest risk of exposure (RR = 2.07, 95% CI: 1.56-2.74).

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

65. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

66. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Levaquin.

67. As a result of Defendants' actions, Plaintiff and, upon information and belief, Plaintiff's treating physicians were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

68. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Levaquin. Defendants were under a duty to disclose the true character, quality, and nature of Levaquin because this was non-public information over which Defendants had and continues to have exclusive control, and because Defendants knew that this information was not available to the Plaintiff, medical providers and/or to their facilities. In addition, Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

¹ Etminan M, Brophy JM, Samii A. Oral fluoroquinolone use and risk of peripheral neuropathy: A pharmacoepidemiologic study. *Neurology* 2014; Epub 2014 Aug 22.

69. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, promoting and/or distributing a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations. Accordingly, Defendants are precluded by the discovery rule and/or the doctrine of fraudulent concealment from relying upon any statute of limitations.

70. For each Count hereinafter alleged and averred, the above and following Paragraphs should be considered re-alleged as if fully rewritten.

COUNT I

[Strict Liability]

71. Levaquin was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Levaquin failed to warn of the dangerous risks posed by Levaquin, including the risk of developing irreversible peripheral neuropathy.

72. At all times alleged herein, Levaquin was defective and Defendants knew that Levaquin was to be used by consumers without inspection for defects. Moreover, Plaintiff, his prescribing physicians, and his health care providers neither knew nor had reason to know at the time of Plaintiff's use of Levaquin of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

73. At all times alleged herein, Levaquin was prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

74. The design of Levaquin was defective in that the risks associated with using Levaquin outweighed any benefits of the design. Any benefits associated with the use of Levaquin were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results.

75. The defect in design existed when the product left Defendants' possession.

76. At the time Levaquin left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting Levaquin.

77. As a result of Levaquin's defective condition, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT II

[Product Liability – Failure to Warn]

78. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

79. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Levaquin, and through that conduct have knowingly and intentionally placed Levaquin into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff who ingested it.

80. Defendants did in fact sell, distribute, supply, manufacture, and/or promote Levaquin to Plaintiff and to his prescribing physicians. Additionally, Defendants expected the Levaquin that they were selling, distributing, supplying, manufacturing, and/or promoting to reach – and Levaquin did in fact reach – prescribing physicians and consumers, including Plaintiff and his prescribing physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

81. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and ingested by Plaintiff. The defective condition of Levaquin was due in part to the fact that it was not accompanied by proper warnings regarding the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of its use.

82. This defect caused serious injury to Plaintiff, who used Levaquin in its intended and foreseeable manner.

83. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

84. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

85. Defendants negligently and recklessly failed to warn of the nature and scope of the side effects associated with Levaquin, namely irreversible peripheral neuropathy.

86. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that Levaquin caused serious injuries, they failed to exercise reasonable care to warn of the dangerous side effect of developing irreversible peripheral neuropathy from Levaquin use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with their failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of Plaintiff.

87. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

88. Defendants, as the manufacturers and/or distributors of the subject product, are

held to the level of knowledge of an expert in the field.

89. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

90. Had Defendants properly disclosed the risks associated with Levaquin, Plaintiff would have avoided the risk of irreversible peripheral neuropathy by not using Levaquin.

91. As a direct and proximate result of the carelessness, negligence, recklessness, and gross negligence of Defendants alleged herein, and in such other ways to be later shown, the subject product caused Plaintiff to sustain injuries as herein alleged.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT III

[Negligence]

92. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

93. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Levaquin.

94. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

95. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

- a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Levaquin;
- b) In failing to warn or instruct, and/or adequately warn or adequately

- instruct, users of the subject product, including Plaintiff herein, of Levaquin's dangerous and defective characteristics;
- c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the subject product;
 - d) In promoting the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause irreversible peripheral neuropathy;
 - e) In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;
 - f) In failing to perform appropriate pre-market testing of the subject product;
 - g) In failing to perform appropriate post-market surveillance of the subject product;
 - h) In failing to adequately and properly test Levaquin before and after placing it on the market;
 - i) In failing to conduct sufficient testing on Levaquin which, if properly performed, would have shown that Levaquin had the serious side effect of causing irreversible peripheral neuropathy;
 - j) In failing to adequately warn Plaintiff and his healthcare providers that the use of Levaquin carried a risk of developing irreversible peripheral neuropathy;
 - k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of Levaquin; and
 - l) In failing to adequately and timely inform Plaintiff and the healthcare

industry of the risk of serious personal injury, namely irreversible peripheral neuropathy, from Levaquin ingestion as described herein.

96. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

97. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT IV

[Breach of Express Warranty]

98. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

99. Before Plaintiff was first prescribed Levaquin and during the period in which he used Levaquin, Defendants expressly warranted that Levaquin was safe.

100. Levaquin did not conform to these express representations because Levaquin was not safe and had an increased risk of serious side effects, including irreversible peripheral neuropathy, whether taken individually or in conjunction with other therapies.

101. As a direct and proximate result of this wrongful conduct, Plaintiff was injured as described above.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein

incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT V

[Breach of Implied Warranty]

102. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

103. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold Levaquin, and prior to the time that it was prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff that the subject product was of merchantable quality and safe and fit for the use for which it was intended.

104. Plaintiff, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

105. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

106. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after he used it.

107. Contrary to the implied warranty for the subject product, Levaquin was not of merchantable quality, and it was neither safe nor fit for its intended uses and purposes, as alleged herein.

108. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his

favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VI

[Fraud]

109. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

110. Defendants misrepresented to Plaintiff, his prescribing physicians, and the healthcare industry the safety and effectiveness of Levaquin and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of Levaquin.

111. Defendants made misrepresentations and actively concealed adverse information when Defendants knew, or should have known, that Levaquin had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physicians, and the healthcare industry generally. Specifically, Defendants actively concealed from Plaintiff, his prescribing physicians, the health care industry, and the consuming public that:

- (a) As early as 1996, Defendants and/or their predecessors were in possession of data (e.g., Hedenmalm, et al.) demonstrating that fluoroquinolones, including Levaquin, increase the risk of irreversible peripheral neuropathy but Defendants actively concealed that information by failing to include it in their labeling for Levaquin at the time the drugs were initially approved by the FDA or at any time thereafter until the FDA mandated label change in 2013;
- (b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Levaquin before and after its product launch;
- (c) Levaquin was not fully and adequately tested by Defendants and/or their

predecessor for the risk of developing irreversible peripheral neuropathy;
and

- (d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Levaquin increases the risk of irreversible peripheral neuropathy.

112. These misrepresentations and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

113. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, his prescribing physicians, and the healthcare industry.

114. Defendants made these false representations with the intent or purpose that Plaintiff, his prescribing physicians, and the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well as the general public.

115. At all times herein mentioned, neither Plaintiff nor his physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, his physicians would not have prescribed and Plaintiff would not have utilized the subject product.

116. Plaintiff, his prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of Levaquin that Defendants did suppress, conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of Levaquin. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

117. Defendants had a post-sale duty to warn Plaintiff, his prescribing physicians, and the general public about the potential risks and complications associated with Levaquin

in a timely manner.

118. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin with the intent and specific desire that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Levaquin as a treatment.

119. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested Levaquin and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VII

[Negligent Misrepresentation]

120. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

121. Defendants negligently and/or recklessly misrepresented to Plaintiff, his prescribing physicians, and the healthcare industry the safety and effectiveness of Levaquin and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Levaquin.

122. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that Levaquin had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, his prescribing physicians, the health care industry, and the consuming public that:

- (a) As early as 1996, Defendants and/or their predecessors were in possession of data (e.g., Hedenmalm, et al.) demonstrating that fluoroquinolones, including Levaquin, increase the risk of irreversible

peripheral neuropathy but Defendants failed to include it in their labeling for Levaquin at the time the drugs were initially approved by the FDA or at any time thereafter until the FDA mandated label change in 2013;

- (b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Levaquin before and after its product launch;
- (c) Levaquin was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and
- (d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Levaquin increases the risk of irreversible peripheral neuropathy.

123. These negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

124. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiff, his prescribing physicians, and the healthcare industry.

125. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, his prescribing physicians, and the healthcare industry would rely on them, leading to the use of Levaquin by Plaintiff as well as the general public.

126. At all times herein mentioned, neither Plaintiff nor his physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, his physicians would not have prescribed and Plaintiff would not have utilized the subject product.

127. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of

Levaquin and relied on the absence of information regarding the dangers of Levaquin which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

128. Defendants had a post-sale duty to warn Plaintiff, his prescribing physicians, and the general public about the potential risks and complications associated with Levaquin in a timely manner.

129. Defendants made the representations and actively concealed information about the defects and dangers of Levaquin with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Levaquin as a treatment.

130. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts set forth above, Plaintiff ingested Levaquin and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT VIII

[Fraudulent Concealment]

131. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

132. Defendants committed actual fraud by making material representations that were false, knowing that such material representations were false, and/or with reckless disregard for the truth or falsity of such material representations with the intent that Plaintiff and his prescribing physicians would rely on such material representations.

133. Plaintiff and his prescribing physicians were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material misrepresentations, and Plaintiff was injured as a direct and proximate result.

134. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiff, his prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff and his prescribing physicians would rely on Defendants' misrepresentations. Plaintiff and his prescribing physicians did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiff was injured as a result.

135. At all times herein mentioned, Defendants had a duty to Plaintiff, his prescribing physicians, and the general public to accurately inform them of risks associated with Levaquin because Defendants, as the manufacturer and/or distributor of the subject product, were in a position of superior knowledge and judgment regarding any potential risks associated with Levaquin.

136. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Levaquin at issue in this lawsuit, said breach or breaches constituting fraud because of his propensity to deceive others or constitute an injury to public interests or public policy.

137. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of Levaquin to increase sales of the drug at the expense of informing Plaintiff that, by ingesting Levaquin, he was placing himself at a significantly-increased risk of developing irreversible peripheral neuropathy.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in his favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

PUNITIVE DAMAGES

138. Plaintiff re-alleges all prior paragraphs of the Complaint as if set out here in full.

139. At all times material hereto, Defendants knew or should have known that

Levaquin was inherently dangerous with respect to the risk of irreversible peripheral neuropathy.

140. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Levaquin.

141. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the subject product.

142. At all times material hereto, Defendants knew and recklessly disregarded the fact that Levaquin causes the chronic illness irreversible peripheral neuropathy.

143. Notwithstanding the foregoing, Defendants continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effect.

144. Defendants knew of the subject product's lack of warnings regarding the risk of irreversible peripheral neuropathy, but they intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and/or sell Levaquin without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Levaquin.

145. Defendants' intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable them to weigh the true risks of using Levaquin against its benefits.

146. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff's injuries and damages are permanent and

will continue into the future.

147. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

- (a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;
- (b) For medical, incidental, and hospital expenses according to proof;
- (c) For pre-judgment and post-judgment interest as provided by law;
- (d) For full refund of all purchase costs Plaintiff paid for Levaquin;
- (e) For compensatory damages in excess of the jurisdictional minimum of this Court;
- (f) For consequential damages in excess of the jurisdictional minimum of this Court;
- (g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;
- (h) For attorneys' fees, expenses, and costs of this action; and
- (i) For such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

DATED this ____ of June, 2015

STARK & STARK

Respectfully submitted,

By: /s/ Stephen A. Corr

Stephen A. Corr
Bar ID: PA 65266
777 Township Line Road
Yardley, Pennsylvania 19067
Phone: 267-759-9684
Fax: 267-907-9659
Attorney for Plaintiff

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS GORDON C. OLSOMMER		DEFENDANTS JOHNSON & JOHNSON; JANSSEN RESEARCH & DEVELOPMENT, LLC; and JANSSEN PHARMACEUTICALS, INC.																																																																																																		
(b) County of Residence of First Listed Plaintiff <u>Pike</u> County, PA <i>(EXCEPT IN U.S. PLAINTIFF CASES)</i>		County of Residence of First Listed Defendant <u>Middlesex</u> County, NJ <i>(IN U.S. PLAINTIFF CASES ONLY)</i>																																																																																																		
(c) Attorneys (<i>Firm Name, Address, and Telephone Number</i>) Stephen A. Corr 777 Township Line Rd. Yardley, PA 19067, 267-759-9684		NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.																																																																																																		
		Attorneys (<i>If Known</i>)																																																																																																		
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		Cite the U.S. Civil Statute under which you are filing (<i>Do not cite jurisdictional statutes unless diversity</i>): 28 U.S.C. 1332																																																																																																		
VI. CAUSE OF ACTION		Brief description of cause: strict liability; negligence; breach of express/implied warranty; fraud; fraud conceal; negl. misrep; punitive damages																																																																																																		
VII. REQUESTED IN COMPLAINT:		<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.	DEMAND \$ 75,000.00	CHECK YES only if demanded in complaint: JURY DEMAND: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No																																																																																																
VIII. RELATED CASE(S) IF ANY		(See instructions): JUDGE _____ DOCKET NUMBER _____																																																																																																		
DATE 06/25/2015		SIGNATURE OF ATTORNEY OF RECORD /s/ Stephen A. Corr																																																																																																		
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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44**Authority For Civil Cover Sheet**

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 - United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
 - United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 - Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 - Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

- IV. Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

- V. Origin.** Place an "X" in one of the six boxes.
 - Original Proceedings. (1) Cases which originate in the United States district courts.
 - Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
 - Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 - Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 - Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 - Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 - Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 - Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.